

Human Subjects Committee Guidelines

John Brown University

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Mission of the JBU Human Subjects Committee of the Institutional Review Board

The mission of the JBU Human Subjects Committee (HSC) is to evaluate and monitor research with human participants carried out by JBU faculty, staff, administration, and students. The HSC will attempt to insure compliance with federal regulations regarding the ethical treatment of human participants in research and will serve as an advocate for their safety and well-being. As an institution that respects Christian values, JBU has an obligation to follow the words uttered by Jesus in the gospel of Matthew:

"Teacher, which is the greatest commandment in the Law?" Jesus replied: " Love the Lord your God with all your heart and with all your soul and with all your mind.' This is the first and greatest commandment. And the second is like it: 'Love your neighbor as yourself.' (Matthew 22: 36-39, NIV)

Loving God and one's neighbor demands treating all people with dignity and compassion. The JBU HSC affirms this through careful oversight of the treatment of subjects as unique creations of God.

Note: The JBU Human Subjects Committee is a part of the JBU Institutional Review Board. Throughout this document, HSC and IRB are used synonymously.

Why have a Human Subjects Committee (HSC)?

Beyond the justification set forth in the mission statement of the JBU HSC, a variety of historical events argue for a formal process by which the rights of research participants are protected.

A Short History of Research with Human Participants

During the course of the 20th century, several specific events stimulated governments and funding agencies to consider developing specific guidelines for research with human participants. Some of the best-documented events include:

- **Nazi Medical War Crimes** - Nazi physicians performed a variety of gruesome experiments on concentration camp prisoners including subjecting them to extreme environmental conditions and lethal pathogens.
- **The Tuskegee Syphilis Study** - Disadvantaged, rural black men with syphilis were recruited for study but were misinformed of some aspects of the study and were not given effective treatments for their disease when the treatments became available.
- **The Jewish Chronic Disease Hospital Study** - Patients/Participants received injections of cancer cells to study how persons with debilitated physical conditions fight off invasions of foreign cells. Participants were not told that they were receiving cancer cells.
- **The Willowbrook Study** - Institutionalized children were intentionally infected with the hepatitis virus in order to study its progression.

As a result of incidents such as these, several organizations studied the use of human participants in research and issued guidelines and reports for researchers to use in planning and execution of their work. The most notable are:

- # **The Nuremberg Code (1947)** - This document came about as a result of the Nuremberg Doctor's Trial and set ten conditions to be met before judging research as ethical.
- # **The Declaration of Helsinki (1964)** - An international declaration from the World Medical Association that defined the ethical standards for medical research.
- # **The Belmont Report (1979)** - A set of guidelines written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- # **Code of Federal Regulations, Title 45, Part 46 [The Common Rule] (1991)** - This federal policy covers research supported by many federal agencies.

Issues of Primary Interest at JBU

1. The Belmont Report

For our purposes at JBU, two of the items listed above are of primary interest. First, The Belmont Report, which in short, outlines three fundamental ethical principles researchers should use to guide their work:

- **Respect for Persons** relates to the autonomy of prospective participants. The Belmont Report requires that participants be treated as autonomous agents, and that persons with diminished autonomy need additional protections. Essentially, participants should be capable of making reasoned decisions regarding their participation in research and should be given all of the information that they need to make the decision to participate. The latter concept involves the procedure of *informed consent*. Participants, under most circumstances, formally agree, in writing, to participate after being given information about the requirements of the study and being informed of their rights as participants. Certain populations of potential participants (e.g., children, institutionalized persons) require informed consent from additional sources.
- **Beneficence** means that researchers put the well being of their participants in a position of great importance as they design and implement their studies. Researchers must maximize the benefits to their participants and at the same time, minimize risk.
- **Justice** relates to the complex issue of who bears the risk in a study and who benefits from that risk. Ethical researchers attempt to distribute the risk and benefits without bias and in an equitable fashion. The issue of justice may involve decisions regarding the choice of participants and the interventions they experience or do not experience.

2. Code of Federal Regulations, Title 45, Part 46 (The Common Rule)

The second item of great importance to researchers at JBU is the Code of Federal Regulations, Title 45, Part 46, often referred to as the Common Rule. These regulations outline the specific steps necessary for institutions to comply with the ethical treatment of human participants in research. CFR, Title 45, Part 46 describes the operations of an Institutional Review Board and it is from these guidelines that JBU derives its plan for the operation of its HSC.

General Guiding Principles in the Common Rule

In a general sense, the most important factors guiding ethical treatment of human participants in research involve the following:

- **Risk/benefits analysis.** Risks to participants should be reasonable in relation to the anticipated benefits of the study.

- **Informed Consent.** Voluntary informed consent should be sought from potential participants or their legally authorized representative. Waiver of informed consent may be granted under certain circumstances.
- **Withdrawal of Consent.** Participants may request that their participation be terminated at any time and that their data be removed from the database.
- **Confidentiality and Privacy.** Researchers should take all possible steps to maintain the confidentiality and privacy of participants.
- **Dignity of the Participants.** Participants should be treated with the utmost dignity and respect at all times.

If researchers keep these factors foremost on their minds while designing and implementing their research, participants of that research should be protected from harm.

Administrative Guidelines

Establishing the HSC and its membership

The JBU Human Subjects Committee (HSC) will consist of at least 5 members appointed by the President based on recommendations submitted by the VPAA. One of the members will act as chair. The chair should be familiar with the process of research with human participants and with the ethical guidelines outlined in federal statutes. All members of the HSC must complete one of the online tutorials (or equivalent) sponsored by the National Institutes of Health (see page 13 for additional information). There should be no more than two HSC members from the same JBU department. One member of the JBU HSC should be an off-campus representative. The HSC reports to the VPAA or a person to be designated by the VPAA. In the event that members of the HSC have a conflict of interest in a particular proposal, those members will recuse themselves from deliberating on the proposal. At the discretion of the HSC chair, individuals with special expertise may be recruited to assist in the review of a protocol. These individuals do not have a vote on the committee.

It is important for the JBU HSC to be a diverse group. Gender and discipline diversity will be important considerations in determining HSC membership.

All research at JBU must be evaluated for its compliance with acceptable methods of ethical treatment of participants. All HSC members will evaluate protocols that require full HSC Review. Protocols that are judged by the HSC Chair to warrant Expedited Review will be sent to individual members of the HSC for evaluation. If a protocol requires evaluation by an individual whose expertise is not represented by committee members, the HSC Chair may ask for an evaluation by a non-committee member.

HSC Meetings

The JBU HSC will, at a minimum, meet once a month in a face-to-face meeting. Additional meetings may be called if deemed necessary by the chair. A quorum of the HSC shall consist of more than half the total membership and is required for votes on protocols.

HSC Records

The HSC will keep written and/or electronic records of proposals, minutes of meetings, and other activities. All records will be kept for three years after the completion of the project.

Definitions

Definitions of concepts relevant to the research approval process can be found in Appendix A.

JBU HSC Guidelines and Information for Researchers

IMPORTANT NOTE: Researchers may not recruit participants, distribute consent forms or begin data collection before receiving approval for the research via the procedures outlined below.

All members of the faculty, staff, administration, and student body who plan to implement research with human subjects must complete HSC Protocol Review Forms (See pages 23-28). Members of the faculty, staff, and administration must then submit their completed forms to the Chair of the HSC.

HSC Decisions

Approved Protocols

Research protocols that are approved by the HSC must be implemented within **one year** of the approval date.

Disapproved Protocols

Protocols disapproved by the HSC will be sent back to the researcher. The HSC may request additional information and/or make suggestions to the researcher for bringing the protocol into compliance.

Appeals for Disapproved Protocols

In the event that a researcher chooses to appeal a decision made by the HSC, the VPAA or a designate of the VPAA will appoint an Appellate HSC to review the proposal. The appeal will be governed by such rules and procedures as this ad hoc review board may establish.

Making Changes to an Approved Protocol

Researchers who wish to make changes in an approved protocol must submit a written request to the HSC Chair.

Cooperative Research

Cooperative research involving investigators from institutions other than JBU must be approved by the investigators' respective HSCs.

Completed Research

When investigators finish an approved research project a “Completion of Research” form should be submitted to the HSC Chair.

Continuing Research

Research that continues beyond one year must be reviewed by the HSC for recertification.

Noncompliance With HSC Regulations

Researchers who fail to comply with the published HSC Regulations will be reported to the VPAA or the VPAA’s designate.

Types of HSC Review

Exempt

Exempt research is research that does not require expedited or full HSC review. *It does require submission of Research Protocol Forms found in on pages 23-28.*

Unless otherwise required by department or agency heads, research activities are exempt from this policy if the only involvement of human subjects will be in one or more of the following categories:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures, or observation of public behavior**, if data are recorded so that subjects cannot be identified in any way, and that there will be no disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
EXCEPTIONS: Research that collects responses from subjects regarding sensitive aspects of personal behavior (e.g., illegal conduct, drug use, sexual attitudes or behavior, use of alcohol, rape, incest, racial attitudes) must undergo either full or expedited review. Also, research that involves psychologically invasive procedures such as detailed personality inventories must undergo either full or expedited review.
- (3) Research involving the use of survey procedures, interview procedures, or observation of public behavior if the human subjects are elected or appointed public officials or candidates for public office.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified in any way.
- (5) Taste and food quality evaluation and consumer acceptance studies.

Expedited Review

Expedited Review involves examination of the research protocol by the chair of the HSC or the chair's designated HSC member when the following conditions are met:

- (1) No more than minimal risk to subjects is involved. Minimal Risk means that the probability or magnitude of physical or psychological harm does not exceed that encountered in ordinary daily life or during routine physical or psychological examinations or tests.
- (2) Where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (3) The standard requirements for informed consent (or its waiver, alteration, or exception) have been met.

Previously approved protocols in which the Principle Investigator desires minor changes during the time of approval (1 year or less) may be eligible for expedited review.

Research Eligible for Expedited Review

Brief descriptions of the research categories for expedited review are listed below (more detailed descriptions are provided in Appendix B):

- (1) The collection of data through noninvasive procedures routinely employed in clinical practice (e.g., moderate exercise, muscular strength testing, flexibility testing, physical sensors, testing sensory acuity).
- (2) The collection of data from voice, video, digital, or image recordings made for research purposes.
- (3) Research on individual or group characteristics or behavior (e.g., research on perception, motivation, identity, cultural beliefs, social behavior) or research employing survey, interview, oral history, program evaluation, or quality assurance methodologies.
- (4) Research involving materials (data, documents, or records) that have been collected or will be collected solely for non-research purposes.
- (5) Prospective collection of biological specimens by noninvasive means (e.g., hair and nail clippings, deciduous teeth, excreta, and external secretions).
- (6) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds.

Full HSC Review

Research protocols will be subjected to full HSC review under the following circumstances:

- (1) Research that does not meet the criteria for being Exempt or eligible for Expedited Review will undergo review by the entire membership of the HSC.
- (2) Research that involves special populations of participants (see page 12 for a list of these groups)

Examples of Research that would Require Full Review

- (1) Studies that involve manipulation of the subjects' mood for the purpose of studying mood changes on a particular behavior.
- (2) Surveys that request information about the subjects' mental illness history
- (3) Surveys or studies that collect information on sensitive personal issues such as sexual behavior or illegal behavior
- (4) Studies that involve deception of subjects
- (5) Any surgical process
- (6) Administration of drugs, chemicals, or biological agents, or devices
- (7) Use of controlled substances
- (8) Administration of physical stimuli
- (9) Major changes in diet or exercise
- (10) Deprivation of physiological requirements such as nutrition or sleep

Special Populations

Research with certain populations necessitates additional scrutiny by researchers and HSC Members. Those groups as identified by Federal Regulations include, but are not limited to:

- Children
- Persons who are cognitively impaired
- Prisoners
- Pregnant Women
- Elderly
- Economically/Educationally Disadvantaged

Research by JBU faculty, staff, administration, or students using any of these groups requires Full HSC Review. In addition to the submission of the usual HSC materials, researchers using any of these populations may be required to obtain signed Informed Consent from the legal representative of the subjects, **AND** preferably, Assent from the subject.

When working with children, researchers may obtain oral assent at around age 4 or 5 and written assent by about age 7 or 8.

Specific Requirements for Student Research

Faculty Requirements

Members of the JBU community who require student research as part of a course requirement should become **HSC Certified**. HSC Certification prepares research sponsors to perform an initial review of student protocols and organize them for submission to the HSC. To become HSC Certified, sponsors must complete an online Human Participant Protection Program. The National Institutes of Health provide a variety of online opportunities for researchers to educate themselves about the issues and practices associated with the ethical treatment of human subjects.

A course approved for this purpose can be found at
<<http://phrp.nihtraining.com/users/login.php>>

When sponsors complete this training they should print out their certificate of completion and submit a copy of it to the Chair of the HSC. Sponsors who do so will be considered HSC Certified.

Recertification is required every two years by completing an online course on research ethics or by completing an equivalent activity as specified by the HSC.

Student Requirements

Students implementing research with human subjects must have a faculty sponsor who will act as immediate supervisor of the research and co-signatory on all HSC materials. Students implementing research that **is not part of a credit-earning course** must submit completed HSC forms containing their sponsor's signature to the Chair of the HSC.

Student research that is implemented as part of a **course requirement** will be subject to the following procedures:

1. Students will fill out all appropriate HSC forms.
2. Students will submit those forms to the instructor of the course.
3. The instructor, who assumes the role of sponsor of the research, will review the protocols and sign the submitted forms. Instructors will organize their students' protocols into three categories: Exempt, Expedited, and Full Review (see page 9-11). The protocols should then be forwarded to the HSC Chair for review.

Informed Consent

General requirements for informed consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. Basic elements of informed consent. Except as provided in paragraph (B) or (C) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

C. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (i) public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- (2) The research could not, in practice, be carried out without the waiver or alteration.

- (3) The research involves no more than minimal risk to the subjects;
- (4) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (5) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

D. The IRB may waive the requirement for a signed consent form if:

- (1) The only record linking the subject to the research would be the consent document and the primary risk is the potential harm resulting from a breach of confidentiality. For example, if a study of adults consists of a survey and the only identifying information on the survey is a signature on a consent form, the requirement of a written consent can be waived by a statement such as, “*I understand that returning this completed survey constitutes my informed consent to participate in this research.*”
- (2) The research must constitute no more than minimal risk.

E. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Adverse Events Involving Research Subjects

- A. Investigators are responsible for notifying the HSC Chair in writing of any adverse events occurring to research subjects as a result of their participation in a research study under the jurisdiction of the HSC.

- B. The written adverse event report should include the following:
 - 1. The date, time, and place of the adverse event.
 - 2. A description of how the event occurred.
 - 3. A description of the adverse event or injury.
 - 4. The events/actions that occurred following and in response to the adverse event, both immediate and long-term action.
 - 5. The names and addresses of witnesses to the event.
 - 6. Any follow up action.
 - 7. The individuals or parties, including health care professionals, notified of the adverse event.
 - 8. Any copies of reports submitted to individuals or parties regarding the adverse event.

- C. The written adverse event report is to be submitted to the HSC Chair within 24 hours.

Currently, the contact person is:

Daniel Bennett, Ph.D.
HSC Chair
John Brown University
Siloam Springs, AR 72761
Phone: 479-524-7142
Email: irb@jbu.edu

APPENDIX A

Definitions

Research: A systematic investigation, including research development, preliminary research (pilot studies), testing and evaluation, designed to develop or contribute to generalized knowledge whether or not funded or supported [45CFR 46.102(d)].

1. **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) data through intervention or interaction with the individual, or
 - (2) identifiable private information. [45CFR 46.102(f)]

Note: Data which are already in existence, publicly available, and free of all identifiers prior to the research study are *secondary data* and do not involve human subjects, and therefore, the IRB does not need to be informed in any way. If you are not sure if you are using secondary data, contact the HSC Chair.
2. **Identifiers:** Any material that would allow a subject in a research study to be identified either directly or through identifiers linked to the subject. This could include signed consent forms, test protocols, instruments, demographic data, and computer files with identifiers. When possible do not record identifying information about subjects.
3. **Intervention:** Both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
4. **Interaction:** Includes communication or interpersonal contact between investigator and subject.
5. **Private information:** Information about a person or behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information provided by an individual for specific purposes which the individual can reasonably expect will not be made public. When recording private information, *coding precautions* should be used to protect individual identities. The codes should be kept in a separate location from the data.
6. **At Risk:** To be placed in a position with greater potential for physical, mental, social, legal, or financial harm than would be expected for that individual in his or her normal occupation or daily activities.
7. **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. [45CFR 46.102(I)]

8. **Informed Consent:** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.
9. **Permission:** The agreement of the parent(s) or guardian(s) to the participation of their child or ward in research. [45CFR46.402]
10. **Assent:** An affirmative agreement to participate in research by a subject not able to give personal consent for reasons of age, mental state, legal, or other such status. Mere failure to object should not be construed as assent. [45CFR46.402]
11. **Children:** Persons who have not attained the legal age for consent (those under 18 years of age).

APPENDIX B

Research Categories for Expedited Review¹

- (1) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- (2) Prospective collection of biological specimens for research purposes by noninvasive means:

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- (3) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (4) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- (5) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (6) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
- (7) Continuing review of research previously approved by the convened IRB as follows:
 - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.
- (8) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#). Source: [63 FR 60364-60367, November 9, 1998](#).

John Brown University

Human Subjects Committee

Cover Sheet

(This cover sheet must be attached to the HSC Protocol Form when submitted for HSC review.)

Title of Project: _____

Principal Researcher: _____

Co-Researcher: _____

Co-Researcher: _____

Faculty Sponsor: _____

Researcher Status: Faculty Administration Staff Student

Project Type: Faculty Research Staff/Admin Research
 Student independent Research Student Course Research

Is this research receiving extramural funding? No Yes Specify

Starting Date for The Research: _____ Projected Completion Date: _____3

For HSC use only:

- Exempt. No further review unless protocol changes
- Approved.
- Approved with Special Conditions, see attachment.
- Not Approved.

Project #: _____

Signed by HSC Chair

Date

V. Participant Selection

1. Describe in detail the characteristics of your participants. How and why were these participants chosen? Approximately, how many participants will be involved in your study?
2. Describe in detail the method/approach you will use to contact all potential participants (initial contacts and any other potential subjects) requesting that they take part in your research AND how they will know they can comfortably decline or let you know they want to participate.
3. Are any of your participants under the age of 18? No Yes If yes, you must have signed consent from the participant's legal representative AND, in most cases, assent from the participant (see page 12 of the Guidelines for details).
4. Will the participants receive any compensation or inducement to participate in this research? If so, describe.

VI. Informed Consent

1. The following information must be included in any procedure: Identification of researcher; institutional affiliation and contact information; identification of HSC Chair and contact information; purpose of the research; expected duration of the subject's participation; description of procedures; risks/benefits; how confidentiality will be ensured; a statement that participation is voluntary and that the subject may withdraw consent at any time without penalty or loss of benefits to which the subject is entitled. (See "Informed Consent", pages 15-17)
2. What type of consent will you be using?
 Signed Consent, Parent/Guardian Permission, Assent. Attach copy of form.
Modified Informed Consent (e.g., implied consent on survey, oral consent). Attach copy of form.
 Oral Consent. Attach copy of script.
 Waiver of consent. Attach justification of waiver request.
3. Describe the methods to be used to ensure the confidentiality of data.
4. Will the participants in this study be exposed to more than minimal risk? Minimal Risk is defined as risk of harm no greater, considering probability and magnitude, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Describe and risks or discomforts that may be associated with participation in this study. What steps have been taken to minimize them?
5. Is any information regarding the research purposely being withheld from the subjects or is deception being used? No Yes. If yes, state the information that will be withheld and/or what deception procedures will be used. Justify the withholding of information and/or deception and describe the post-research debriefing in detail.

Researcher Agreement

I/We certify that the information contained in this Protocol Form is accurate and that all procedures were developed to minimize risk and/or discomfort of the participants. I/We agree to be vigilant throughout the research process for any adverse reactions of participants and to report those reactions to the Chair of the JBU HSC.

I/We understand that any deviation from an approved protocol and/or any research beyond one year of approval must be submitted for review.

Signature of Researcher

Date

If this is a student project:

Signature of Student's Sponsor

Date

Send completed proposal to:

Daniel Bennett, Ph.D.
Chair, HSC
John Brown University
Siloam Springs, AR 72761
Phone: 479-524-7142
E-mail: irb@jbu.edu